UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

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DAVID CHRISTENSON and
ANNIKEN PROSSER,

Plaintiffs,

Case No. 20-cv-194

v.

ALEX AZAR, in his capacity as Secretary of the United States Department of Health and Human Services,

Defendant.

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MEMORANDUM IN SUPPORT OF DEFENDANT'S CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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## I. INTRODUCTION

Plaintiffs David Christenson and Anniken Prosser suffer from glioblastoma multiforme ("GBM"), an incurable form of brain cancer. This case arises from an Administrative Law Judge's denial of their respective claims for Medicare coverage of certain months of tumor treatment field therapy ("TTFT"),[1] which uses electric fields to prevent tumor growth. Plaintiffs raise a single issue on appeal: whether the Secretary of the Department of Health and Human Services (the "Secretary") is forever collaterally estopped from denying plaintiffs' TTFT claims because an ALJ allowed coverage for certain months of TTFT claims.

The doctrine of collateral estoppel does not, as plaintiffs assert, apply to these kinds of administrative decisions, and to do so would be inconsistent with the design of the Medicare

[1] As discussed below, plaintiffs are not financially responsible for paying for the TTFT claims at issue if Medicare does not cover it.

program, which handles 1.2 billion Medicare claims per year[2] and covers over 60 million Americans.[3] The United States cannot be estopped on the same terms as a private litigant, and the Supreme Court never upheld an assertion of offensive collateral estoppel against the United States. *Heckler v. Cmty. Health Servs. of Crawford Co., Inc.*, 467 U.S. 51, 60 (1984); *United States v. Mendoza*, 464 U.S. 154 (1984). Plaintiffs are asking that a series of non-precedential decisions from ALJs forever estop the Secretary from denying claims for TTFT treatment to these plaintiffs. In so arguing, plaintiffs rely on *Astoria Federal Savings and Loan Association v. Solimino*, 501 U.S. 104 (1991), which held that an administrative decision, regarding an age discrimination claim, did *not* have preclusive effect because to apply collateral estoppel would be against Congress' intent in enacting the relevant statute. Indeed, plaintiffs fail to cite any cases on point, yet the Seventh Circuit as well as the Fourth, Fifth, Ninth, and D.C. Circuits have followed the Supreme Court's reasoning and rejected similar attempts to bind federal agencies to non-precedential decisions in administrative appeals.

To permit collateral estoppel would interfere with the discretion and deference afforded to the Secretary to implement the Medicare statute, run contrary to the Medicare statute's presentment and channeling requirements, and conflict with the Appropriations Clause of the U.S. Constitution. Moreover, even if there was no bar to collateral estoppel, Plaintiffs have failed to meet all four required elements. The issues in the ALJ decisions are not the same because the coverage determinations are limited to specified time periods. The same issues were not actually

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[2] *See* What is a MAC?, https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/What-is-a-MAC (last visited April 27, 2020).

[3] *See* Medicare Enrollment Dashboard, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Dashboard/Medicare-Enrollment/Enrollment%20Dashboard.html (last visited April 27, 2020).

litigated because the ALJ decisions specify that they apply to only the specific claims for Medicare coverage before the tribunal. In addition, because of the limits on when the Secretary can appear in ALJ hearings, the Secretary did not have a full and fair opportunity to litigate the issues. Plaintiffs have forfeited any other issues for judicial review.[4] The Secretary respectfully requests summary judgment be granted in the Secretary's favor and that Plaintiffs' motion be denied.

## II. STATUTORY AND REGULATORY FRAMEWORK

### A. "Reasonable and Necessary" Medicare Expenses

Medicare is a federal health insurance program for the aged and disabled. *See* 42 U.S.C. § 1395 *et seq*. Original "fee-for-service" Medicare consists of two parts: Part A, 42 U.S.C. § 1395c *et seq.*, which pays for inpatient hospital and related post-hospital benefits, and Part B, 42 U.S.C. § 1395j *et seq.*, which provides a voluntary supplemental insurance program for payment of various other types of care, including coverage for certain types of durable medical equipment (DME) for qualified recipients. 42 U.S.C. §§ 1395k, 1395x(s)(6).

For a medical service to be covered by Medicare, it must fit within a benefit category established by the Medicare statute. 42 U.S.C. § 1395k. The various benefit categories available under Medicare Part B are further set forth in 42 C.F.R. part 410. Medicare coverage is also subject to 42 U.S.C. § 1395y(a)(1)(A), which excludes certain items from coverage. Under this section, "no payment may be made under . . . part B of this subchapter for any expenses incurred for items or services[] which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . . ." 42 U.S.C.

[4] Plaintiffs have forfeited any argument that the ALJ decisions were not supported by substantial evidence by failing to make the argument in their motion for summary judgment. In the event that Plaintiffs subsequently raise the issue and the Court determines the argument has not been forfeited, the Secretary reserves his right to brief those issues on the merits.

§ 1395y(a)(1)(A). Unless there is an exception, this bar applies "[n]othwithstanding any other provision" of the Medicare statute. *Id.* The Centers for Medicare & Medicaid Services (CMS), which administers the Medicare program for the Secretary, has historically interpreted "reasonable and necessary" to mean that an item or service must be safe and effective, medically necessary and appropriate, and not experimental in order to qualify for reimbursement. *See* Medicare Program Integrity Manual (MPIM) § 13.5.4.[5]

To administer the "reasonable and necessary" standard, the Secretary employs a range of tools, from formal regulations to informal manuals. In choosing among these options, the Secretary is not required to promulgate regulations or policies that, "either by default rule or by specification, address every conceivable question" that may arise. *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 96 (1995). The Secretary may articulate "reasonable and necessary" standards through formal regulations that have the force and effect of law throughout the administrative process. *See* 42 U.S.C. §§ 1395hh; 1395ff(a)(1). The Secretary may also issue National Coverage Determinations (NCDs) "with respect to whether or not a particular item or service is covered nationally." 42 U.S.C. § 1395ff(f)(1)(B); *see also* 42 C.F.R. §§ 400.202, 405.1060.

### B. Enforcement of the "Reasonable and Necessary" Standard Through Local Coverage Determinations (LCDs)

The Secretary has delegated to CMS broad authority to determine whether Medicare covers particular medical services. *See* 42 U.S.C. §§ 1395y(a), 1395ff(a), (f). CMS, in turn, contracts with Medicare Administrative Contractors (MACs), such as CGS Administrators in this case, to

[5] The MPIM is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf. The MPIM "is a compilation of guidelines which CMS issues to instruct Medicare contractors on how to conduct medical review of Medicare claims submitted by Medicare providers and suppliers for payment." *Erringer v. Thompson*, 371 F.3d 625, 628 (9th Cir. 2004).

administer certain day-to-day functions of the Medicare program. 42 U.S.C. § 1395kk-1. Consistent with controlling regulations and NCDs, a MAC makes coverage determinations, issues payments, and develops LCDs for the geographic area it serves, *see* 42 U.S.C. § 1395ff(f)(2)(B), in accordance with the reasonable and necessary provisions in 42 U.S.C. § 1395y(a)(1). *See* 42 U.S.C. §§ 1395kk-1(a)(4). An LCD is binding only on the contractor that issued it, and only at the initial stages of the Medicare claim review process, as opposed to later stages if a claimant should appeal a determination by a MAC. 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II).

In developing LCDs, such as the one at issue in this case, MACs follow guidance contained in the MPIM. The MPIM requires MACs to publish LCDs that specify when "an item or service is considered to be reasonable and necessary." MPIM § 13.5.4. MACs develop LCDs by considering medical literature, the advice of local medical societies and medical consultants, public comments, and comments from the provider community. MPIM §§ 13.2.3, 13.5.2.1, 13.5.3, 13.5.5; 66 Fed. Reg. 58,788, 58,788 (Nov. 23, 2001). MACs also follow detailed procedures for issuing new or substantively revised LCDs, including engaging in a comment-and-notice period, soliciting feedback and recommendations from the medical community, and presenting the policy in meetings of stakeholders. MPIM § 13.2.1.

New LCDs require both a notice period and a comment period. MPIM § 13.2.4.2. The MAC first issues a draft LCD and provides the public a minimum of 45 days to comment on it. LCDs are principally based upon "available evidence of general acceptance by the medical community, such as published original research in peer-reviewed medical journals, systematic reviews and meta-analyses, evidence-based consensus statements and clinical guidelines." MPIM § 13.5.3. After considering all of the comments and revising the LCD as needed, the contractor

publishes the final LCD, providing at least a 45-day notice period before the LCD goes into effect. *Id*. at § 13.2.6.

### C. The LCD for TTFT Devices

As set forth in the administrative record, both plaintiffs have glioblastoma multiforme (GBM), a kind of brain tumor. AR 4225, 5389. In April 2011, the United States Food and Drug Administration approved the marketing of a tumor treatment field therapy (TTFT) device called NovoTTF-100A, later rebranded Optune. AR 293. This device is manufactured by Novocure, for the treatment of recurrent GBM. AR 293, 298–322. Three years later, following an open meeting and solicitation of public comments, in August 2014, the DME MACs issued the original LCD for TTFT. AR 133. "The DME MACs determined that, based on the strength and quality of the evidence available at that time, TTFT was not reasonable and necessary for the treatment of GBM." *Id.* The LCD in effect at the relevant time, *i.e.*, during the dates of service for the claims on appeal, remained substantively unchanged and stated that "Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary." AR 98.[6]

In 2018, Novocure requested that the DME MACs approve Medicare payment of TTFT for newly diagnosed GBM. AR 118, 124. Effective September 1, 2019, the LCD was revised to permit coverage for newly diagnosed GBM and continued coverage for newly diagnosed GBM beyond the first three months of therapy in certain circumstances.[7] Novocure was "extremely

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[6] The previous LCD is available at: https://localcoverage.cms.gov/mcd_archive/view/lcd.aspx?lcdInfo=34823%3a12 (last visited April 27, 2020)

[7] The 2019 LCD is available at: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34823&ver=27&DocID=L34823&bc=gAAAAAgAAAAA& (last visited April 27, 2020).

pleased" with the 2019 LCD and notes that its coverage criteria "is generally similar to Optune's commercial coverage criteria for newly diagnosed GBM."[8]

### D. Administrative Review Process for Medicare Claims

CMS, through its contractors, processes millions of Medicare claims each year. To ensure efficiency and economy, Congress has required that a multi-level administrative claims and appeals process be exhausted before a Medicare beneficiary may seek judicial review. 42 U.S.C. § 1395ff; *see also Heckler v. Ringer*, 466 U.S. 602, 627 (1984). As the statutory and regulatory framework establishes, a Medicare beneficiary who seeks to challenge a denial of coverage must first request a redetermination of the denial by a Medicare contractor. 42 U.S.C. § 1395ff(a)(3)(B)(i); 42 C.F.R. §§ 405.904(a)(2), 405.948. Next, the beneficiary may request reconsideration by a qualified independent contractor (QIC). 42 U.S.C. §§ 1395ff(c)(1), (2); 42 C.F.R. § 405.960. The QIC's panel members must have "sufficient medical, legal, and other expertise, including knowledge of the Medicare program." 42 C.F.R. § 405.968(c)(1); *see* 42 U.S.C. § 1395ff(b)(1)(A), 1395ff(c); 42 C.F.R. § 405.960. An LCD is not binding at this and at higher levels of appeal. 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II); 42 C.F.R. § 405.968(b). After reconsideration, the beneficiary may request a hearing before an administrative law judge (ALJ). *See* 42 U.S.C. § 1395ff(b)(1)(A); 42 C.F.R. § 405.1002. Last, the beneficiary may request that the Medicare Appeals Council, a division of the Departmental Appeals Board of the U.S. Department of Health and Human Services, review the ALJ's decision. 42 C.F.R. § 405.1100. The MAC's decision represents the final decision of the Secretary. 42 C.F.R. § 405.1130.

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[8] *See* Medicare Releases Final Local Coverage Determination Providing Coverage of Optune® for Newly Diagnosed Glioblastoma, https://www.novocure.com/medicare-releases-final-local-coverage-determination-providing-coverage-of-optune-for-newly-diagnosed-glioblastoma/ (last visited April 27, 2020).

### E. Advanced Beneficiary Notices

If Medicare coverage is denied, Medicare will nevertheless pay the claim if neither the supplier nor the beneficiary knew or could reasonably have been expected to know that the item would not be covered. 42 U.S.C. § 1395pp; 42 C.F.R. § 411.400(a). However, the supplier is expected to be familiar with Medicare laws, regulations, and policies. 42 C.F.R. § 411.406. If the supplier should reasonably have known a claim would not be covered, Medicare is not responsible. 42 C.F.R. § 411.400(a). The supplier can shift the risk of non-coverage to the beneficiary by providing him with advance written notice (called an "Advance Beneficiary Notice") of the specific reason why the item probably will not be covered. 42 C.F.R. § 411.404(b). As the ALJs found in the decisions on review, because Novocure did not require Plaintiffs to sign an Advance Beneficiary Notice, no matter the outcome of this case, they will not be financially responsible for the TTFT claims at issue. AR 74, 4284.

## III. FACTUAL AND PROCEDURAL BACKGROUND

### A. David Christenson

Plaintiff David Christenson was diagnosed with glioblastoma multiforme (GBM) in July 2015. AR 96. He was initially treated with chemotherapy, radiation, and surgery, but his GBM recurred. AR 96, 203. In January 2016, he was prescribed the use of the TFTT device and temozolomide as treatment for his recurrent GBM. AR 96, 4225. As of February 2017, he uses only the TFTT device. AR 96, 4227. An MRI in September 2018 showed that Mr. Christenson's condition is stable. AR 96, 203, 206. Novocure, the supplier of TFTT, rents the device to Mr. Christenson on a monthly basis. AR 189.

CGS Administrators, the Medicare Administrative Contractor responsible for processing these claims, denied coverage for TTFT claims dated November 13, 2018, December 3, 2018, and

January 3, 2019. AR 95, 210, 247–49. The denial was based on LCD 34823, which provides that TTFT is not covered because it is not reasonable and necessary. AR 4174. On March 11, 2019, CGS affirmed the denial on redetermination and found Novocure liable for the cost. AR 240–42. On appeal, the QIC also upheld the denial of the claims and found Novocure liable. AR 4167–4178. Novocure and counsel for the beneficiary appealed the denial to an ALJ on June 14, 2019. AR 169, 179.

ALJ Scott Watson held a hearing on August 28, 2019. AR 95; AR 4217. Counsel for the beneficiary and the clinical appeal specialist for Novocure appeared. AR 4221. Representatives of the Medicare Administrative Contractor did not participate. AR 95.

ALJ Watson issued a decision (1-8630709341) on September 12, 2019. *Id*. He held that Medicare Part B did not provide coverage for the TTFT for Mr. Christenson's recurrent GBM and that, as there was no Advanced Beneficiary Notice, Novocure was liable for the charges. AR 99. ALJ Watson explained that ALJs are "not bound by LCDs" but "substantial deference" is given to them if applicable to the case. AR 98. He continued that if an ALJ chooses to disregard an LCD, he "must explain the reasons why" and the decision "applies only to the specific claim being considered and does not have precedential effect." *Id*. ALJ Watson found LCD 34823 applicable, explaining that it addressed TTFT as a treatment for recurrent GBM such as Mr. Christenson's. AR 98. He further found the LCD should be applied to the claims at issue and that TTFT was not reasonable and necessary in this case. *Id.* He acknowledged that the treatment has been effective for Mr. Christenson, but determined that there was not sufficient evidence showing that the LCD was not applicable or should be disregarded. AR 98–99.

Counsel for Mr. Christenson and Novocure appealed the decision to the Medicare Appeals Council, arguing that the previous appeal decided in Mr. Christenson's favor precluded the

unfavorable result and including the prior decisions. AR 5, 61. The ALJ in decision 1-8285652321, decided April 2, 2019, declined to follow the LCD, relying on studies conducted after the LCD was promulgated showing that the treatment was effective. AR 11–18. The ALJ in combined decision 1-8416270832 and 1-8416229632, decided June 6, 2019, also departed from the LCD "under the specific facts of this appeal" because he determined that the evidence showed the treatment was safe and effective. AR 23–30.

The Council notified counsel on January 22, 2020, that it was unable to issue a decision within the regulatory time frame and therefore counsel could escalate review to the district court. AR 1. Mr. Christenson first sought review of ALJ Watson's decision in the District of Columbia, but re-filed in this court as the proper venue.

**B. Anniken Prosser**

Plaintiff Anniken Prosser was diagnosed with GBM in February 2016 after an MRI discovered a tumor. AR 5392. After surgery to remove the tumor she underwent chemoradiation therapy, followed by treatment of temozolomide and TTFT in June 2016. AR 5393. She began using only TTFT in April 2017. *Id*. Her MRIs in 2018 and 2019 show that her condition is stable. *Id.*

CGS Administrators denied coverage for claims dated January 16, 2018, February 16, 2018, March 16, 2018, and April 16, 2018, based on LCD 34823. AR 4310, 5138–41. On July 10, 2018, CGS affirmed the denial on redetermination and found Novocure liable for the cost. AR 5130–32. On appeal, the QIC also upheld the denial of the claims and found Novocure liable. AR 5367–71. Novocure and counsel for the beneficiary appealed the denial to an Administrative Law Judge. AR 4381–87.

ALJ Joseph Grow held a hearing on May 20, 2019. AR 5387. Counsel for the beneficiary and the clinical appeal specialist for Novocure appeared. *Id*. The ALJ issued a decision (1-8390277469) on June 19, 2019. AR 4310–15. He held that Medicare Part B did not cover the TTFT to treat Ms. Prosser's newly diagnosed GBM and that, as there was no Advanced Beneficiary Notice, Novocure was liable for the charges. AR 4314. ALJ Grow found that counsel's arguments amounted "to challenges to the underlying record upon which the LCD is based" which is a separate adjudicative process. *Id*. During the hearing, counsel for the beneficiary responded "yes" that she was challenging the LCD under the regulations that allow LCDs to be reviewed in a separate process. AR 5395. He explained that LCDs are afforded substantial deference such that an ALJ must explain his reasoning if he chose to disregard it. AR 4313. Thus, as the relevant LCD was still in effect, he afforded it substantial deference. AR 4313–14. He further noted that the Medicare Appeals Council, in four nonprecedential decisions, cited the relevant LCD in upholding denials of coverage for TTFT. AR 4313.

On July 12, 2019, counsel for Ms. Prosser and Novocure appealed the decision to the Medicare Appeals Council. AR 4268, 4293. They included other favorable ALJ decisions for Ms. Prosser and argued they precluded the unfavorable result.[9] AR 4238–62.

The Council notified counsel on January 22, 2020, that it was unable to issue a decision within the regulatory time frame and therefore counsel could escalate review to the district court as. AR 4232. Ms. Prosser first sought review of ALJ Grow's decision in the District of Columbia, but re-filed in this court as the proper venue.

[9] In ALJ decision 1-8380637906, decided *after* ALJ Grow's decision, on June 27, 2019, the ALJ declined to follow the LCD based on the medical literature provided during the hearing and Ms. Prosser's success with the treatment. AR 4238–52. In ALJ decision 1-8416188648, decided May 16, 2019, the ALJ declined to follow the LCD base on the medical literature showing it was safe and effective for treating Ms. Prosser's newly diagnosed GBM. AR 4254–62.

## IV. STANDARD OF REVIEW

In reviewing an administrative decision regarding a claim for Medicare benefits, the court reviews the administrative record to determine if the decision is supported by substantial evidence and based on the correct legal standard. 42 U.S.C. § 405(g); *Wood v. Thompson*, 246 F.3d 1026, 1029 (7th Cir. 2011). Substantial evidence is "more than a scintilla" and means "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Wood*, 246 F.3d at 1029 (quoting *Kaputsa v. Sullivan*, 900 F.2d 94, 96 (7th Cir. 1989) (further citations omitted)); *see Martin v. Saul*, 950 F.3d 369, 373 (7th Cir. 2020). In reviewing a denial of Medicare coverage, the Seventh Circuit has cautioned that decisions "made within the context of an extremely technical and complex field" like Medicare are properly entrusted to the "specialized knowledge" of the Secretary. *Wilkins v. Sullivan*, 889 F.2d 135, 140 (7th Cir. 1989).

The court's review is also limited to the administrative record, which the Secretary is responsible for certifying and filing. 42 U.S.C. §§ 405(g), 1395ff(b)(1)(A) (explaining the Secretary shall file "a certified copy of the transcript of the record including the evidence upon which the findings and decision complained of are based"); *Luna v. Shalala*, 22 F.3d 687, 689 (7th Cir. 1994); *see Fed. Power Comm'n v. Transcon. Gas Pipe Line Corp.*, 423 U.S. 326, 331 (1976). The exhibits attached to Plaintiffs' motion for summary judgment should therefore not be considered, particularly as Plaintiffs' exhibits include a number of documents, at Exhibits H, J, L, and M, that were not before the ALJs and are not a part of the record.

## V. ARGUMENT

Plaintiffs seek a "sentence four" remand, which allows the court to enter a judgment affirming, modifying, or reversing the Secretary's decision, arguing that the earlier favorable ALJ decisions preclude the unfavorable decisions in 1-8630709341 and 1-8390277469, and in any coverage decisions going forward. Pls. Br. *See* 42 U.S.C. § 405(g); *Melkonyan v. Sullivan*, 501

U.S. 89, 99–100 (1991). In asserting that collateral estoppel can and should apply to ALJ decisions, Plaintiffs ignore the principle that preclusion cannot apply to agency decisions when there is a statutory purpose to the contrary. *See Astoria*, 501 U.S. at 108. Application of offensive collateral estoppel in this case would interfere with the discretion and deference afforded to the Secretary to implement the Medicare statute, run contrary to the Medicare statute's presentment and channeling requirements, and conflict with the Appropriations Clause of the U.S. Constitution. Furthermore, the elements of collateral estoppel are not present and it would be unfair to apply collateral estoppel against the Secretary. Finally, even if collateral estoppel applied, it would have no force after the new LCD became effective September 1, 2019.

### A. Collateral Estoppel is Inapplicable to Medicare Claim Appeals

Plaintiffs rely heavily on the Supreme Court's decision in *Astoria* to press its argument that the favorable ALJ decisions should have preclusive effect, but they omit that the Court held the agency decision in question had no preclusive effect. Pls. Br. at 3. 501 U.S. at 106. There the Court explained that agency decisions should not be given preclusive effect when there is a statute expressing a contrary intent on the issue of preclusion. *Id.* at 108. *See Duvall v. Atty. Gen. of U.S.*, 436 F.3d 382, 387-88 (3d Cir. 2006) (stating that collateral estoppel cannot be applied if it would "frustrate congressional intent or impede the effective functioning of the agency."). At issue in *Astoria* was whether, under the Age Discrimination in Employment Act, "the judicially unreviewed findings of a state administrative agency decision" precluded re-litigation in federal court. 501 U.S. at 106. The Court noted that the statute required plaintiffs to pursue their claims under state law first and that state administrative proceedings had to be concluded before bringing suit in federal court. *Id*. at 111. Therefore, the Court concluded, it was safe to assume "the

possibility of federal consideration after state agencies have finished theirs." *Id*. If the state agency decision was given preclusive effect, the "federal proceedings would be strictly *pro form*a." *Id*.

Plaintiffs rely on several other cases for the assertion that collateral estoppel should apply to unreviewed ALJ decisions denying Medicare benefits, but they are inapposite. Pls. Br. 3–4. *B & B Hardware, Inc. v. Hargis Industries*, 575 U.S. 138 (2015), involved private parties, and the Court did not consider whether the federal government may be bound by administrative decisions. *Continental Can Co. v. Marshall*, 603 F.2d 590 (7th Cir. 1979) was decided well before *Astoria*, and therefore fails to perform the required analysis of whether there was a statute prohibiting collateral estoppel. *See B & B Hardware*, 575 U.S. at 148 (applying *Astoria*'s rule that issue preclusion cannot be applied if there is a statute preventing it). *Bowen v. United States*, 570 F.2d 1311, 1319–20 (7th Cir. 1978), was decided pursuant to Indiana's collateral estoppel law and, in contrast to the statutes in this case, Indiana law specifically stated that a federal administrative agency decision finding violations of air safety rules also constituted a state law violation because the state law incorporated the federal standard. In effect, the statute required collateral estoppel rather than prohibiting it. The court in *C & N Corporation v. Kane*, 953 F.Supp.2d 903 (E.D. Wisc. 2013), like *B & B Hardware*, 575 U.S. 138, did not consider whether the federal government may be bound by administrative decisions; it only considered whether private parties could be bound. Finally, the Supreme Court later explicitly held in *B & B Hardware* that the type of administrative decision at issue in *C & N Corporation* could be preclusive only because the Lanham Act did not prohibit it. 575 U.S. 138 (2015). Significantly, Plaintiffs have cited no previous case in which collateral estoppel was applied to a Medicare coverage determination.

1. *Federal regulations provide that ALJ decisions do not bind the Secretary in future cases.*

The Medicare statute and regulations bar the application of collateral estoppel to ALJ decisions. In fact, the Medicare regulations sharply distinguish between a narrow category of precedential decisions that are binding on future administrative appeals and the remainder of nonprecedential decisions that are not binding. In Medicare coverage cases, only Council-level decisions have the potential to become precedential, which occurs only if they are so designated by the Chair of the Departmental Appeals Board. 42 C.F.R. § 401.109. Council decisions designated as precedential must be made available to the public, with personally identifiable information removed, and notice of precedential decisions must be published in the Federal Register. 42 C.F.R. § 401.109(b). That decision is then given "precedential effect" and is binding on "all HHS components that adjudicate matters under the jurisdiction of CMS." *Id.* § 401.109(c).[10] The term "precedential effect" means that the Council's:

> (1) Legal analysis and interpretation of a Medicare authority or provision is binding and must be followed in future determinations and appeals in which the same authority or provision applies and is still in effect; and
>
> (2) Factual findings are binding and must be applied to future determinations and appeals involving the same parties if the relevant facts are the same and evidence is presented that the underlying factual circumstances have not changed since the issuance of the precedential final decision.

*Id.* § 401.109(d). Accordingly, the term "precedential effect" is synonymous with a decision having binding or preclusive effect. It is undisputed that no Council decision, much less one designated as precedential, has favorably decided Plaintiffs' claims.

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[10] HHS is the United States Department of Health and Human Services.

The regulations governing LCDs further support that the ALJ decisions are nonbinding and therefore collateral estoppel does not apply. Plaintiffs' collateral estoppel argument relies upon a favorable ALJ decision that departed from the LCD when approving TTFT treatment.[11] But in this circumstance, governing regulations provide that an ALJ's decision to depart from an LCD "applies only to the specific claim being considered and does not have precedential effect." 42 C.F.R. § 405.1062(b); 70 Fed. Reg. 11420, 11458 (Mar. 8, 2005) ("[T]he ALJ or [Council] may decline to follow a policy in a particular case, but must explain the reason why the policy was not followed. These decisions apply only for purposes of the appeal in question, and do not have precedential effect."). The regulations re-affirm that only "[p]recedential decisions designated by the Chair of the Departmental Appeals Board in accordance with § 401.109 of this chapter, are binding . . . ." 42 C.F.R. § 405.1063(c). Indeed, ALJ decisions are not even binding on lower levels of administrative review, such as the QIC second level of review. *See* 42 C.F.R. § 405.968(b) (omitting ALJ decisions among the rulings that bind the QIC).

Giving preclusive effect to ALJ decisions is also contrary to the Medicare statute, which provides that the Council must "review the case de novo." 42 U.S.C. § 1395ff(d)(2)(B); *see Porzecanski v. Azar*, 943 F.3d 472, 477 (D.C. Cir. 2019) ("Because the review generally binds only the parties unless specifically designated as precedential, a favorable determination in one proceeding does not ensure that future claims will be approved.") (citing 42 C.F.R. §§ 401.109, 405.1130, 405.1048). If a favorable ALJ ruling collaterally estopped the Council from denying a beneficiary's claim for the same treatment, the Council could not perform a de novo review; instead, the Council would be bound to accept the ALJ's conclusions. *See Almy v. Sebelius*, 679

[11] ALJs are not bound by LCDs, but are required to afford them "substantial deference." 42 C.F.R. § 405.1062(a). ALJs are not authorized to "set aside or review the validity of an . . . LCD for purposes of a claim appeal." *Id.* § 405.1062(c).

F.3d 297, 310 (4th Cir. 2012) (concluding that the Council's obligation to undertake "de novo" review was "incompatible with [plaintiff's] proffered notion that the [Council] is somehow obligated to defer to the outcomes of prior decisions below").

This is in line with the guidance from The Restatement (Second) of Judgments § 83 (1982)[12] that:

> (4) An adjudicative determination of an issue by an administrative tribunal does not preclude relitigation of that issue in another tribunal if according preclusive effect to determination of the issue would be incompatible with a legislative policy that:
>
> > (a) The determination of the tribunal adjudicating the issue is not to be accorded conclusive effect in subsequent proceedings; or
> >
> > (b) The tribunal in which the issue subsequently arises be free to make an independent determination of the issue in question.

Medicare regulations clearly state ALJ decisions are not to be accorded conclusive effect as they are non-precedential, and the Council's de novo review means it is free to make an independent determination. Accordingly, the Medicare statutes and regulations bar the application of collateral estoppel to the ALJ decisions.

2. *Applying collateral estoppel would interfere with the discretion and deference afforded to the Secretary to implement the Medicare statute.*

If ALJ decisions were to be deemed binding, this ruling would run contrary to the deference and discretion afforded to the Secretary to implement the Medicare statute, particularly as pertains to the "reasonable and necessary" standard for coverage of items and services furnished to program beneficiaries. *See Wilkins,* 889 F.2d at 140 (in discussing review of denial of Medicare benefits, court said "It is precisely this type of decision—made within the context of an extremely technical and complex field—that courts should leave in the hands of expert administrators. . . . Congress

[12] The Supreme Court has noted it "regularly turns" to this Restatement for guidance on issue preclusion. *B&B Hardware v. Hargis Indus.*, 575 U.S. 138, 148 (2015).

delegated these difficult decisions to agencies that have developed specialized knowledge.") "[T]he choice made between proceeding by general rule or by individual, *ad hoc* litigation is one that lies primarily in the informed discretion of the administrative agency." *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947). The Medicare statute and regulations preserve "this discretion for the Secretary, leaving it to her judgment whether to proceed by implementing an NCD, by allowing regional contractors to adopt an LCD, or by deciding individual cases through the adjudicative process." *Almy*, 679 F.3d at 303. The Supreme Court has foreclosed arguments that interfere with this discretion, holding that "[t]he Secretary's decision as to whether a particular medical service is 'reasonable and necessary' and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions." *Ringer*, 466 U.S. at 617; *see also Guernsey Mem'l Hosp.*, 514 U.S. at 97 ("The Secretary's mode of determining benefits by both rulemaking and adjudication is, in our view, a proper exercise of her statutory mandate.").

As noted above, the Medicare regulations designate ALJ decisions as non-binding and non-precedential, which allows individual adjudication over Part B claims. Generally speaking, this inures to the benefit of Medicare beneficiaries, who, even after repeated denials of similar claims, have the right to de novo review of any subsequent claims. The application of collateral estoppel would be fundamentally inconsistent with individual adjudication of Part B claims. In Plaintiffs' view, once a claim for benefits is approved, the Secretary would be estopped from ever denying a claim for the same treatment. Pls. Br. at 18. Individual adjudication would be impossible, because the earliest-in-time ALJ ruling would forever bind the Secretary. Accordingly, it is within the Secretary's discretion *not* to be bound by ALJ rulings. *See generally Ringer*, 466 U.S. at 607–08 (distinguishing between ALJ and Council-level decisions that "applied only to the claimants

involved in that case and [were] not to be cited as precedent in future cases" and a subsequent formal administrative ruling by the Secretary that bound ALJs and the Council).

Here, the Secretary's decision that ALJ decisions are non-binding and non-precedential is expressed in the plain, unambiguous language of the applicable law and regulations. *See Avalon Place Trinity*, DAB No. 2819, at 13 (2017) ("An unappealed ALJ decision [does not set] a precedent binding on ALJs or the Board. When the *Board* has not reviewed the ALJ decision, the *Board* has not issued a decision in that case. Regardless of whether an ALJ decision was appealed to the Board, an ALJ decision is not precedential and does not bind the Board, and is relevant in later cases only to the extent its reasoning is on point and persuasive.") (italics in original), *aff'd*, *Avalon Place Trinity v. HHS*, 761 F. App'x 407 (5th Cir. Mar. 4, 2019). Because giving preclusive effect to ALJ rulings would contravene the Medicare regulations, the Court should decline to apply collateral estoppel here.

While Plaintiffs fails to cite any cases on point,[13] this Circuit as well as the Fourth, Fifth, Ninth, and D.C. Circuits have each rejected similar attempts to bind federal agencies to non-precedential decisions in lower-level administrative appeals. *See Abraham Memorial Hosp. v. Sebelius*, 698 F.3d 536, 556 (7th Cir. 2012) ("The handful of prior Board decisions the Hospitals rely upon to purportedly show HHS's long-standing policy are not determinative. Our precedent

[13] Plaintiffs' reliance on the unpublished decision in *Brewster v. Barnhart*, 145 F. App'x 542 (6th Cir. 2005) is misplaced. Pl. Br. at 4. The court found that, under circumstances unique to Social Security disability appeals, an applicant (not the government) was bound by an ALJ's earlier finding concerning the exertion level of the applicant's past work. *Id.* at 546–48. Plaintiffs' additional citation, Pl. Br. at 4, to a case concerning the unique circumstances of immigration appeals is similarly unhelpful. *Islam v. U.S. D.H.S.*, 136 F. Supp. 3d 1088 (N.D. Cal. 2015). Among other things, unlike the Medicare statute and regulations' prohibition on collateral estoppel here, the *Islam* court determined that the Immigration and Nationality Act permitted collateral estoppel of issues decided by an Immigration Judge in granting asylum. *Id.* at 1093–94. Additionally, unlike here, the other elements of collateral estoppel were actually met in *Islam*. *Id.* at 1091–93.

instructs that Board decisions are not the decisions of the Secretary or her Administrator and are not authoritative."); *Homemakers North Shore, Inc. v. Bowen*, 832 F.2d 408, 413 (7th Cir. 1987) ("'The Secretary's position' is the position of the Department as an entity, and the fact that people in the chain of command have expressed divergent views does not diminish the effect of the agency's resolution of those disputes. An inconsistent administrative position means flipflops by the agency over time, rather than reversals within the bureaucratic pyramid.").

In *Almy*, plaintiff asserted that Council decisions denying coverage for a medical device created a policy of denying treatment for that device. 679 F.3d at 299. The Fourth Circuit disagreed, noting that "[t]he Secretary's own regulations make clear that any policy implications in an adjudication do not have precedential effect. . . . The purported 'policy' in this case is nothing more than the accretion of individual decisions finding that the [device] does not meet the statutory requirements for coverage." *Id.* at 303 (citing 42 C.F.R. § 405.1062). The Court noted that Congress gave the Secretary discretion to "decide how to deal with hundreds of millions of Part B claims for coverage of thousands of devices every year." *Id.* at 304. Likewise, this court should reject Plaintiffs' attempt to elevate nonprecedential ALJ opinions into binding coverage rules, which would "stultify the administrative process." *Id.* (quoting *Chenery*, 332 U.S. at 202).

In *Almy*, the Court noted that other circuits have concluded that "[t]here is no authority for the proposition that a lower component of a government agency may bind the decision making of the highest level . . . [E]ven if these cases were found to evince internal inconsistency at a subordinate level, the [agency] itself would not be acting inconsistently." *Id.* at 310 (quoting *Community Care Found. v. Thompson*, 318 F.3d 219, 227 (D.C. Cir. 2003)). Along the same lines, the D.C. Circuit has emphasized its "well-established view that an agency is not bound by the actions of its staff if the agency has not endorsed those actions." *Comcast Corp. v. FCC*, 526 F.3d

763, 769 (D.C. Cir. 2008) (citing cases). Instead, "a definitive and binding statement on behalf of the agency must come from a source with the authority to bind the agency." *Devon Energy Corp. v. Kempthorne*, 551 F.3d 1030, 1040 (D.C. Cir. 2008); *see, e.g.*, *Freeman v. U.S. Dep't of the Interior*, 37 F. Supp. 3d 313, 344–45 (D.D.C. 2014) (finding that "unappealed" ALJ rulings could not estop the United States because such rulings were not binding on the agency or even on other ALJs and noting that the lack of appeal did not "elevate them to the level of a binding final agency action").

The Ninth Circuit explicitly adopted the reasoning in *Almy*, reversing a district court decision that "incorrectly measured agency inconsistency across" ALJ decisions. *Int'l Rehab. Sci. Inc. v. Sebelius*, 688 F.3d 994, 1001 (9th Cir. 2012); *see also County of Los Angeles v. Leavitt*, 521 F.3d 1073, 1079 (9th Cir. 2008) (noting that "intermediary interpretations are not binding on the Secretary, who alone makes policy"). The Fifth Circuit reached the same conclusion. *See Homan & Crimen, Inc. v. Harris*, 626 F.2d 1201, 1205 (5th Cir. 1980) ("[T]he decision of the [Provider Reimbursement Review Board] carries no more weight on review by the Secretary than any other interim decision made along the way in an agency where the ultimate decision of the agency is controlling.").

In sum, "Congress has delegated broad authority to the Secretary to determine when a device is reasonable and necessary, as well as broad authority to select the procedures used for making that determination. The decisions of local contractors cannot deprive her of that discretion, any more than the diverse decisions of district courts or courts of appeals throughout the country could bind the Supreme Court." *Almy*, 679 F.3d at 311. The doctrine of collateral estoppel cannot transform an ALJ ruling from what it is—a decision by an intermediate-level tribunal that is only

binding in a single case—to what it is not, an officially binding statement of policy by the Secretary. To do so would be contrary to the Medicare statute and regulations.

3. *Collateral estoppel is contrary to the Medicare statute's presentment and channeling requirements*

To the extent that Plaintiffs seek to have the Secretary collaterally estopped as to future claims for TTFT, the D.C. Circuit in *Porzecanski* recently held that the Medicare statute prohibits a Medicare beneficiary from obtaining "prospective equitable relief mandating that HHS recognize his treatment as a covered Medicare benefit in all future claim determinations." 943 F.3d at 475.

The facts in *Porzecanksi* are similar to those in the instant case. Porzecanski suffered from a rare, life-threatening condition with no known cure and started on an experimental regimen of a biological product. *Id.* at 476. At the time, there was a dearth of scientific testing supporting the product for plaintiff's symptoms; nonetheless, during the course of plaintiff's treatment, the product came to be considered the best available treatment. *Id.* After beginning treatment, Porzecanski remained symptom-free and his physicians recommended that he continue the monthly treatment indefinitely. *Id.* at 476–77. After one of his claims was denied at the ALJ level and the Council did not render a decision within the required time frame, plaintiff filed in federal court. *Id.* at 477. While the federal case was pending, plaintiff continued to submit monthly Medicare claims, which were approved by a QIC or ALJ. *Id.* On appeal of his denied claim, plaintiff sought declaratory and injunctive relief confirming his entitlement to Medicare coverage for the product and requiring the Secretary to provide Medicare benefits. *Id.*

The D.C. Circuit held that plaintiff could not "satisfy § 405(g)'s presentment requirement with respect to future claims because those claims have not yet arisen." *Id.* at 482. Because Medicare claims can only be filed after the medical service has been furnished, and section 405(g) requires appeals from "decision[s]" of the Secretary, the presentment requirement could not be

met: "[T]he Secretary has not decided [plaintiff's] future claims because – to state the obvious – none has been submitted." *Id.*

The court also rejected plaintiff's request to preclude the Secretary from concluding that the claims on appeal were not covered by Medicare and were not medically necessary—the same relief that Plaintiffs seek here. *Id.* at 482 (finding plaintiff's "strained position" to be "at odds with Supreme Court precedent."). In support, the D.C. Circuit relied on two Supreme Court decisions: *Ringer* and *Illinois Council*. In *Ringer*, "the Court held that § 405(g) barred a patient from obtaining declaratory and injunctive relief compelling the Secretary to conclude that his future surgery was 'reasonable and necessary' under the Medicare Act." *Id.* (citing 466 U.S. at 620–21). Although the patient sought equitable relief, it was "essentially one requesting the payment of benefits." *Id.* (quoting 466 U.S. at 620). Any claim seeking to establish a right of future payments constitutes a "claim arising under" the Medicare Act. *Id.* (citing 466 U.S. at 621). Likewise, in *Illinois Council*, the Court again declared that a "claim for future benefits is a § 405(h) claim" and that "all aspects" of any future claim "must be channeled through the administrative process." *Id.* (citing 529 U.S. at 12).

The D.C. Circuit thus concluded, "*Ringer* and *Illinois Council* directly foreclose [plaintiff's] attempt to recast the requested relief as anything other than a claim for future benefits." *Id.* at 483. Likewise, Plaintiffs' assertion that the Secretary is estopped from denying their future claims for TTFT treatment "runs headlong into the Supreme Court's instruction that 'all aspects' of a claim be first channeled through the agency." *Id.* (quoting *Illinois Council*, 529 U.S. at 12). Plaintiffs cannot leverage a favorable ALJ decision to estop the Secretary from denying "future claims for the same reasons." *Id.* at 483–84.

4. *Collateral estoppel is contrary to the Appropriations Clause of the U.S. Constitution*

The Appropriations Clause of the Constitution, Art. I, § 9, cl. 7, provides that: "No Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law." In *Office of Personnel Management v. Richmond*, 496 U.S. 414 (1990), the Supreme Court held that the government, despite the erroneous oral and written representations of a federal employee, was not equitably estopped from determining that a claimant who exceeded the statutory limit on earnings was ineligible for disability benefits. The Supreme Court concluded:

> Whether there are any extreme circumstances that might support estoppel in a case not involving payment from the Treasury is a matter we need not address. As for monetary claims, it is enough to say that this Court has never upheld an assertion of estoppel against the Government by a claimant seeking public funds. In this context, there can be no estoppel, for courts cannot estop the Constitution.

*Id.* at 434. *See also Columbus Reg'l Hosp. v. FEMA*, 708 F.3d 893, 899 (7th Cir. 2013) (agency employee could not commit agency to pay what was not permitted by statute and regulations); *Briscoe ex rel. Taylor v. Barnhart*, 425 F.3d 345, 356–57 (7th Cir. 2005) (explaining that "payment from U.S. Treasury must be authorized by statute").

Courts have applied the holding in *Richmond* to the Medicare context. In *Monongahela Valley Hospital v. Sullivan*, 945 F.2d 576 (3d Cir. 1991), the Third Circuit held that *Richmond* foreclosed a Medicare provider's estoppel claim against the Secretary for additional Medicare reimbursement. *Id.* at 588–89. Likewise, in *Downtown Medical Center/Comprehensive Health Care Clinic v. Bowen*, the Tenth Circuit declined to estop the Secretary and a private insurer, which processed Medicare claims on the Secretary's behalf, from denying the plaintiff's reimbursement claim. 944 F.2d 756, 771 (10th Cir. 1991). *See also Almy*, 679 F.3d at 312 ("It is the Secretary,

not the courts, who bears the responsibility for the disbursement of billions of dollars of public money under the Medicare system.").

The same reasoning applies to Plaintiffs' assertion of collateral estoppel. Plaintiffs seek to estop the Secretary from denying their claims payment from the Medicare Trust Fund. Of course, no appropriation of Congress entitles Plaintiffs to future payments from the Medicare Trust Fund. Because Plaintiffs seek to draw money from the Treasury on equitable grounds, the Court must deny their assertion of collateral estoppel.

**B. The Elements of Collateral Estoppel are Not Met**

Even if collateral estoppel could be invoked in this case, the elements have not been met. As an initial matter, ALJ Decision 1-8380637906, which Ms. Prosser submitted in support of her appeal to the Council, was decided eight days *after* ALJ Grow's decision, and can therefore have no preclusive effect. AR 4238–52. *See Adams v. City of Indianapolis*, 742 F.3d 720, 736 (7th Cir. 2014) (collateral estoppel "applies to prevent relitigation of issues resolved in an *earlier* suit") (emphasis added). Plaintiffs' argument that the later decision can be preclusive because it is "final" first, is without merit. Pls. Br. at 23. Appealing a decision, as Ms. Prosser did with ALJ Grow's decision, does not defeat the finality of the judgment. *Ross ex rel. Ross v. Bd. of Educ. Of Twp. High Sch. Dist. 211*, 486 F.3d 279, 284 (7th Cir. 2007).

As the party invoking collateral estoppel, it is plaintiffs' burden to show:

> (1) the issue sought to be precluded [was] the same as that involved in prior litigation,
> (2) the issue was actually litigated,
> (3) the determination of the issue [was] essential to the final judgment, and
> (4) the party against whom estoppel is invoked [was] fully represented in the prior action

*In re Calvert*, 913 F.3d 697, 701 (7th Cir. 2019)(citing *Matrix IV, Inc. v. Am. Nat'l Bank & Trust Co. of Chi*., 649 F.3d 539, 547 (7th Cir. 2011) (further quotations omitted). Plaintiffs have not carried their burden on the first, second, and fourth elements.

1. *The issues are not the same.*

First, because each ALJ decision concerns whether the TTFT treatment was covered by Medicare for a specific period of time, the issues in the appealed cases are not the same. Mr. Christenson is appealing (ALJ decision 1-8630709341) the denial of coverage for November 13, 2018, December 3, 2018, and January 3, 2019. AR 49–53. The other ALJ decisions do not cover this time period. AR 11–30. The same is true for Ms. Prosser. AR 4238–62. She appeals (ALJ decision 1-8390277469), which denied coverage for January 16, 2018, February 16, 2018, March 16, 2018, and April 16, 2018. AR 4310–15. Every favorable ALJ decision cited by Plaintiffs notes that the decision is limited to specific coverage dates. AR 11, 15, 24, 29, 4239, 4250, 4255, 4262. The time period of coverage is a key aspect of the ALJ decisions given that beneficiaries' medical conditions can change. The Seventh Circuit, in *Rucker v. Chater*, 92 F.3d 492, 495 (7th Cir. 1996), found that, in review of an application for Social Security disability benefits, an ALJ's determination that the claimant had the residual functional capacity (RFC) for sedentary work did preclude the ALJ in her second application (made while the district court reviewed the first denial) from determining she had the RFC for medium work. The court explained that the first ALJ's finding "was a binding determination with respect to Rucker's eligibility for disability benefits for that period. *It has no effect, however, on an application for disability benefits for a subsequent time period*." *Id*. (emphasis added). Because each ALJ decision in this case addresses a different time period, the issues were not the same and collateral estoppel cannot be invoked. *See, e.g.*, *In re Grand Jury Proceedings of Special Apr. 2002 Grand Jury*, 347 F.3d 197, 202 (7th Cir. 2003)

(finding collateral estoppel did not apply because appellant's state of mind during the prior grand jury proceedings where he refused to testify were not dispositive of his current state of mind in refusing to testify before a new grand jury even if he listed similar objections); *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 435 F.3d 1356, 1361–62 (Fed. Cir. 2006) (declining to apply collateral estoppel where patent infringement involved two distinct time periods).

2. *The same issue was not actually litigated.*

As to the second element, again the differing time periods covered by each ALJ decision means that same issue was not actually litigated. The prior favorable decisions explicitly limited the time period of the coverage decisions, as do the Medicare regulations limiting the precedential effect of ALJs declining to follow an LCD, 42 C.F.R. § 405.1062(b). AR 11, 29–30, 4262. As such, plaintiffs cannot meet the second element. *See Donovan v. Fed. Clearing Die Casting Co*., 695 F.2d 1020, 1022 (7th Cir. 1982) (issue not actually litigated when issue left expressly undecided by decision); *Interoceanica v. Sound Pilots*, 107 F.3d 86, 91–92 (2d Cir. 1997) (finding issue not actually litigated or decided where prior decision explicitly stated it did not reach an issue); *California Communities Against Toxics v. EPA*, 928 F.3d 1041, 1052 (D.C. Cir. 2019) (finding issues not actually litigated where court stated it did "need not address" the issue).

3. *The Secretary was not fully represented in the prior actions.*

Finally, the fourth element is not met because the Secretary's opportunity to litigate is limited in Medicare coverage appeals. He cannot participate in the first two levels of the administrative appeals process. *See* 42 C.F.R. §§ 405.948, 405.968. *See Genesis Health Ventures, Inc. v. Sebelius*, 798 F. Supp. 2d 170, 182 (D.D.C. 2011) ("[I]f an intermediary finds coverage and pays a claim, there is never an administrative appeal, and the Secretary would have no knowledge of the intermediary's decision nor opportunity to review those actions."). The Secretary's

participation is also limited in ALJ appeals. When a beneficiary is unrepresented, the Secretary cannot be a party to the hearing. 42 C.F.R. § 405.1012(a). If the Secretary does not affirmatively elect to participate or become a party in ALJ proceedings, the proceedings move forward without the Secretary's involvement. 42 C.F.R. §§ 405.1010(a), 405.1012(b). Although the Secretary may participate or become a party in ALJ hearings involving beneficiaries represented by counsel, it is impracticable for the Secretary to litigate the over 400,000 Medicare claim appeals filed each year at the ALJ level. 42 C.F.R. §§ 405.1010(a), 405.1012; *see supra* n.2. *See* U.S. Government Accountability Office Report at 1, 12 (May 2016), https://www.gao.gov/assets/680/677034.pdf (last visited April 17, 2020); *also* 82 Fed. Reg. 4974, 4976 (Jan. 17, 2017) (noting that there were 650,000 pending ALJ appeals as of September 2016). If the Secretary does not become a party to an ALJ hearing, it cannot appeal a favorable ruling to the Council. 42 C.F.R. §§ 405.1012, 405.1102(a)(1), (d). In other words, the Secretary would need to litigate every ALJ hearing in order to have the right to appeal any decisions favorable to the beneficiary. Therefore, as the Secretary's opportunity to appeal was extremely limited, there was not a full and fair opportunity to litigate.

4. *The lack of incentive to litigate the ALJ decisions weighs against preclusion.*

Courts have also recognized an exception to applying preclusion even where all the elements for estoppel are met. Where there is an incentive against extensively litigating smaller matters (because cost outweighs the size of the issue), it is unfair to allow the decisions in those smaller matters to have large preclusive effects. Such is the case here, where the Secretary's involvement in the litigation of every claim would be an inefficient use of resources better put towards the Medicare program. Unreviewed and nonprecedential ALJ decisions should not be given preclusive effect, which would result in great cost to the Medicare Trust. *See Power Integrations v. Semiconductor Components Indus.*, 926 F.3d 1306, 1312, 1313 (Fed. Cir. 2019)

(holding that the exception of "a lack of opportunity or incentive to litigate the first action" prevented preclusion where there was a disparity in incentives to appeal an issue); *Rawls v. Daughters of Charity of St. Vincent De Paul*, 491 F.2d 141, 148 (5th Cir. 1974) (no preclusive effect given to habeas corpus hearing finding involuntary hospitalization was illegal in subsequent suit against hospital for false imprisonment because the hospital "had far less incentive to contest the unlawfulness of the plaintiff's detention than at present").

5. *Even if collateral estoppel applied, it would have no further force after the new LCD became effective on September 1, 2019*

Even if collateral estoppel applied here, it would have no force after the new LCD became effective on September 1, 2019. Collateral estoppel generally will not apply when "'controlling facts or legal principles have changed significantly since the [prior] judgment.'" *Karns v. Shanahan*, 879 F.3d 504, 514 (3d Cir. 2018) (alteration in original) (quoting *Montana*, 440 U.S. at 155. Here, there is no doubt that there was a significant change between the old LCD, which categorically denied coverage for TTFT treatment, and the new LCD, which allowed coverage of TTFT under certain circumstances. Accordingly, if Plaintiffs were to prevail on collateral estoppel, only the two ALJ decisions would be affected. Further preclusive or injunctive relief would not be warranted, because the new LCD has already been in place for over six months.

Similarly, the medical context of this case necessarily means that the controlling facts are constantly changing. Physicians do not prescribe treatment, no matter how potentially effective, indefinitely into the future. A treatment that may have been beneficial for a patient at one point in time could be ineffective or dangerous if continued (e.g., when a patient suffers serious side effects). In this case, there is no evidence that the facts supporting Plaintiffs' claims for coverage in 2018 are identical to the facts supporting their claims for coverage in 2020. Even if their medical history remained unchanged for two years, it would be pure speculation to assert that the facts

would remain unchanged for any claim they might file in the future. For example, if Plaintiffs filed claims for coverage, but the evidence showed that they were not actually using the device, Medicare should not be required to approve their claims. AR 127, 4266, 5393.

Because the controlling facts and law have changed, applying collateral estoppel would have zero benefit for Plaintiffs, who are not financially responsible for the claims on appeal. Meanwhile, a finding that favorable ALJ decisions have preclusive effect would have widespread, negative ramifications for the Medicare program, and millions of beneficiaries. Because collateral estoppel is fundamentally inconsistent with the Medicare Program, the court should grant summary judgment for the Secretary.

### C. Plaintiffs Forfeited Any Argument that Substantial Evidence Does Not Support the ALJ Decisions

Finally, Plaintiffs have forfeited any argument that the ALJ decisions 1-8630709341 and 1-8390277469 are not supported by substantial evidence. The Seventh Circuit has held in similar administrative review cases that undeveloped arguments are waived, as are arguments not raised in the initial brief. *See Cent. States, Se. & Sw. Areas Pension Fund v. Midwest Motor Exp., Inc.*, 181 F.3d 799, 808 (7th Cir. 1999) (finding "arguments not developed in any meaningful way are waived."); *Jones v. Shalala*, 10 F.3d 522, 525 n.4 (7th Cir. 1993) (finding waiver where argument not developed in body of brief); *Darif v. Holder*, 739 F.3d 329, 336–37 (7th Cir. 2014) (finding argument waived where raised for the first time in reply brief); *Narducci v. Moore*, 572 F.3d 313, 324 (7th Cir. 2009) (same). Here, plaintiffs have argued only that the doctrine of collateral estoppel requires coverage of all plaintiffs' claims for TTFT. They made no argument that the ALJ decisions were not supported by substantial evidence. In the event plaintiffs attempt to raise the issue later, it should be deemed waived.

## VI. CONCLUSION

For the foregoing reasons, the Secretary respectfully requests that the Court grant his cross-motion for summary judgment and deny Plaintiffs' motion for summary judgment.

Dated at Milwaukee, Wisconsin this 4th day of May, 2020.

Respectfully submitted,

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